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IT support for healthcare processes – premises, challenges, perspectives

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Abstract

Healthcare processes require the cooperation of different organizational units and medical disciplines. In such an environment optimal process support becomes crucial. Though healthcare processes frequently change, and therefore the separation of the flow logic from the application code seems to be promising, workflow technology has not yet been broadly used in healthcare environments. In this paper we elaborate both the potential and the essential limitations of IT support for healthcare processes. We identify different levels of process support in healthcare, and distinguish between organizational processes and the medical treatment process. To recognize the limitations of IT support we adopt a broad socio-technical perspective based on scientific literature and personal experience. Despite of the limitations we identified, undeniably, IT has a huge potential to improve healthcare quality which has not been explored by current IT solutions. In particular, we indicate how advanced process management technology can improve IT support for healthcare processes. © 2006 Elsevier B.V. All rights reserved.

Keywords: Healthcare processes; Medical guidelines; Medical decision support; Workflow management; Adaptive information systems

1. Introduction

Process-oriented information systems have been demanded for more than 20 years [24] and terms like *continuity of care* have even been discussed for more than 50 years. Yet, healthcare organizations are still characterized by an increasing number of medical disciplines and specialized departments. Healthcare processes require interdisciplinary cooperation and coordination. The recent trend towards healthcare networks and integrated care even increases the need to effectively support interdisciplinary cooperation along with the patient treatment process.

Healthcare processes heavily depend on both information and knowledge. Thus, information management plays an important role in this context. Numerous studies have demonstrated positive effects when using IT

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systems in healthcare. In particular the preventability of adverse events in medicine has been in the focus of recent studies. Adverse events are defined as unintended injuries caused by medical management rather than the disease process [83]. It turned out that insufficient communication and missing information are among the major factors contributing to adverse events in medicine [7,13,14,34,87,88]. IT support for healthcare processes therefore has the potential to significantly reduce the rate of adverse events by selectively providing accurate and timely information at the point of care [45]. Yet, there is a discrepancy between the potential and the actual usage of IT in healthcare. A recent IOM¹ report even states that there is an “absence of real progress towards applying advances in information technology to improve administrative and clinical processes” [53].

Why is it so difficult to build IT systems that support a seamless flow of information along healthcare processes? To find appropriate answers to this question it is important to understand the characteristics of healthcare processes. In current literature, however, there is a lot of confusion in this context stemming from different, inconsistent and incomplete perspectives on what healthcare processes are. To identify the core challenges for IT support as well as the shortcomings of current IT solutions we have to distinguish between *organizational processes* (e.g., medical order entry and result reporting) and the *medical treatment process* (e.g., diagnostic and therapeutic procedures to be carried out for a particular patient). While organizational process patterns shall help to coordinate interoperating healthcare professionals and organizational units (e.g., handling of a medical order and result reporting), treatment processes are linked to the patient. Different challenges arise in connection with these different levels.

As different organizational units often have their own specialized IT applications, one of the main challenges for the IT support of organizational processes concerns application integration. We summarize how existing integration standards contribute to process support by providing stable *generic process patterns* and why there is still a large potential for workflow technology.

The specific patient treatment process, in turn, depends on medical knowledge and case specific decisions. Decisions are made by interpreting patient specific data according to medical knowledge. This decision process is very complex, as medical knowledge includes medical guidelines of various kinds and evidence levels, as well as individual experience of physicians. Moreover, medical knowledge continuously evolves over time. It is generally agreed that medical decision making cannot be automated. Yet, the patient treatment process can be improved by selectively providing medical knowledge in the context of this process. The problem is to offer *current* knowledge, to only offer *relevant* knowledge according to the current context, to include the underlying evidence, and to support all of this in a way which seamlessly integrates with the physicians work practice. Current IT solutions are far away from this perspective for various reasons. One of these reasons is the lack of flexibility of current solutions, which is needed to cope with the evolving nature of medical knowledge. Thus it appears to be suitable to improve IT support for healthcare processes by exploiting the features of adaptive process management systems. We discuss the potential offered by next generation process management technology in this context. We sketch how it can contribute to provide full lifecycle support for treatment processes, but we also show which challenges, problems and essential limitations remain.

Section 2 deals with organizational processes in healthcare. It describes how traditional healthcare information systems support organizational process patterns, how standards contribute to integration, and why workflow-based support is still needed. By contrast Section 3 focuses on the medical treatment process and its basic characteristics. We show how treatment processes are influenced by medical knowledge and patient related information, and how current achievements in medical decision support contribute to improve healthcare quality. A practical example is given in Section 4. Section 5 takes a more visionary approach. It discusses implications for future process-oriented IT architectures in healthcare. In particular, we show how adaptive process management technology may contribute to improve IT support for healthcare processes in the long term, and which challenges still need to be addressed. The paper closes with a summary and outlook in Section 6.

¹ Institute of Medicine (IOM) of the National Academies (www.iom.edu).

2. Organizational processes in healthcare

In this section we focus on the support of organizational procedures in hospitals, and exclude issues related to the patient treatment process and the medical knowledge influencing it. We motivate the need for organizational process support in hospitals, give a typical example of a cross-departmental healthcare process, and show how IT support for such cooperative processes is currently realized in practice. Due to the fragmentation of application functions and medical data in hospitals we cannot deal with these issues without considering application integration as well. In recent years, a number of integration and interoperability standards have emerged in healthcare, which provide the basis for the IT-based support of organizational processes in healthcare. Based on these standards and on vendor-independent “reference workflows” several *generic process patterns* (e.g., handling of an imaging encounter) have been suggested. We sketch characteristics of these generic process patterns and discuss to which extent they enable organizational process support. We further look at limitations of this concept which emerge when site-specific adaptations of process implementations become necessary.

2.1. Why hospitals crave for IT support of organizational processes?

In hospitals the work of physicians, nurses, and technicians is significantly burdened by organizational tasks. Medical procedures (e.g., lab tests, imaging encounters) have to be planned and prepared, appointments with different service providers be scheduled, specimen or the patients themselves be transported, visits of physicians from other departments be arranged, and reports be written, transmitted, and evaluated. Thus, the cooperation between people from different departments is a vital task with repetitive, but non-trivial character. Usually, organizational tasks have to be coordinated manually by the clinical personnel necessitating, for example, time-consuming phone calls and documentation steps. In clinical practice, this often leads to organizational problems and to a high administrative load of clinicians. As a consequence, many errors result and unwanted effects occur. Patients may have to wait, because resources (e.g., physicians, rooms, technical equipment) are not available (e.g., due to bad planning). Medical procedures may become impossible to perform if information is missing, preparations are omitted, or a preparatory procedure has been postponed, canceled or requires latency time. Subsequent appointments may then have to be re-scheduled, again resulting in numerous phone-calls and time losses. For all these reasons hospital stays are often longer than required, and costs or even invasiveness of patient treatment are unnecessarily high. Clinical personnel is aware of these problems and process-aware information systems coordinating organizational tasks and providing information at the point of care would be highly welcome. In an increasing way it is being understood, that the correlation between medicine, organization and information is high, and that today’s organizational structures and IT systems offer only sub-optimal support.

2.2. Example of an organizational process

A typical organizational process for medical order entry and result reporting, which is used to coordinate the inter-departmental communication between a ward (ambulatory setting) and the radiology unit, is illustrated in Fig. 1. The depicted process is not tailored to a specific medical pathway (cf. Section 3), but shows an organizational procedure of the hospital. In our example an order is placed by a nurse or a physician at the ward or at an ambulatory setting. In the most general case the indication is checked in the radiology department and depending on the result the order placer is informed whether the request has been rejected or scheduled. The actual radiological examination and the corresponding documentation is done in the examination room. The radiology report is generated afterwards. If necessary some iterations for corrections are passed until the experienced radiologist can validate the report by his signature. The final report is sent back to the order placer.

Procedures like the one described constitute a part of the fundamental processes of clinical practice and mainly capture the organizational knowledge necessary to coordinate the healthcare process among different people and organizational units; i.e., focus is on the support of core organizational processes. Though these

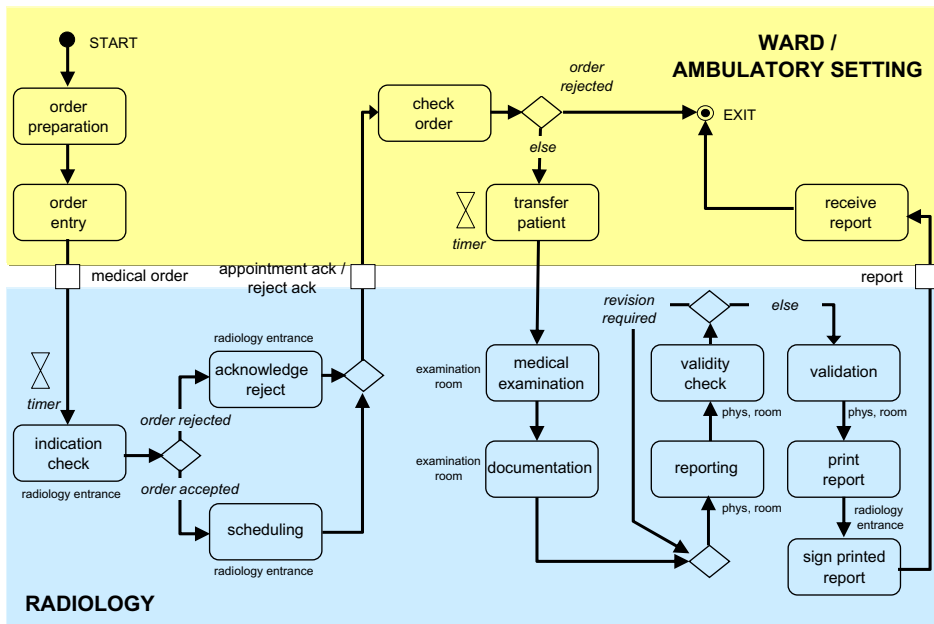


Fig. 1. Example of an organizational process (order entry and result reporting).

processes evolve over time, they remain basically the same for longer periods of time. As we will see in Section 3 this constitutes a significant difference when compared to patient treatment processes.

2.3. IT support for organizational processes

How can organizational processes in healthcare be supported by IT? As indicated above the computerized support of organizational processes is usually closely related to application integration. The reason is that the architecture of typical hospital information systems is characterized by many different departmental systems, which have usually been optimized for the support of different medical disciplines (e.g. radiology, cardiology, or pathology), but not for cross-departmental processes. The need to consolidate the data produced by these ancillary systems to a global patient-centered view and to support the cross-departmental processes has motivated the development of standards for data and message interchange in healthcare. These standards also play an important role when not only cross-departmental but also cross-organizational healthcare processes are to be supported. Today, HL7 is the leading standard for systems integration in healthcare. The name “Health Level 7” refers to the application layer in the OSI reference model [75].

HL7 is a message-based standard for the exchange of data among hospital applications. The standard defines which data items are to be interchanged when certain clinical trigger events occur (e.g., related to the admission, discharge, or transfer of a patient). Since Version 2.3 (1997) the standard has covered trigger events for patient administration, patient accounting, order entry, medical information management, clinical observation data, patient and resource scheduling, and others. The standard has been continuously extended and newly arising topics, such as the integration of genomic data in Electronic Health Records, are handled in special interest groups (SIGs). Yet, the HL7 trigger events are intended to support standard communication patterns that will occur in any healthcare organization in basically the same way. Today’s commercially available healthcare software usually only covers a relatively small portion of HL7, implementing those communication patterns that are typically requested as essential basis for interconnecting disparate applications. Besides HL7 numerous additional standards exist that need to be considered when integrating different kinds of data in the medical domain. Most notably, the DICOM standard (Digital Imaging and Communications in Medicine) has to be mentioned (cf. [46]), which is well accepted for the exchange of medical image data, and partly overlaps in its data definitions with HL7.

Despite well accepted standards for data integration like HL7 and DICOM, healthcare applications are still far from plug and play compatibility (which is essential for the realization of process-oriented healthcare information systems). One reason for this is that existing standards do not address functional integration issues sufficiently. By *functional integration* we refer to the meaningful cooperation of functions of different software components. Uncontrolled data redundancy is often the result of an insufficient functional integration of disparate systems. Autonomously developed systems often overlap in their functionality, partly providing the same or only slightly differing functionality. This aggravates integration even if the systems are already based on common ontologies [38]. In order to avoid these difficulties common *application frameworks* are required which serve as a reference for programmers to create functionally compatible software components. Requirements for an application framework directed towards open systems in the healthcare domain are described in [40]. In general such a framework must provide specifications of interfaces and interaction protocols which are needed for embedding a software component into a system of cooperating components.

The best example for such a standard in the healthcare domain is the IHE initiative (“Integrating the Healthcare Enterprise”) [82]. IHE does not develop new standards for data interchange but specifies so called “integration profiles” on the basis of HL7 and DICOM (see above). Thereby “actors” and “transactions” are defined independently from any specific software product. An integration profile specifies how different actors interact via IHE transactions in order to perform a special task. These integration profiles serve as a semantic reference for application programmers, so that they can build software products that can be functionally integrated into an IHE conformant application framework. IHE is based on HL7 Version 2 and it has already been increasingly adopted by vendors. The core integration profile of IHE is called “Scheduled Workflow”. It establishes a seamless flow of information in a typical imaging encounter (e.g., to generate an X-ray for a patient) by precisely specifying the actors and transactions involved in the process of image acquisition. By fixing the required workflow steps and the corresponding transactions, IHE ensures the consistency of patient information from registration through ordering, scheduling, imaging acquisition, storage, and viewing. This consistency is also important for subsequent workflow steps, such as reporting. However, this kind of process support has nothing to do with the traditional idea of workflow systems – to separate the flow of control from application logic in order to keep the workflow maintainable [17,21,42]. The idea of these standards is to establish stable generic process patterns that help to integrate autonomously developed IT components. Existing implementations are reduced to a minimum and do not provide process management functions (e.g., for process monitoring). Thus, this approach is only applicable to very few organizational procedures, whereas in most cases we need facilities to adapt process implementation to the respective healthcare organization.

3. The medical treatment process

In this section we describe basic characteristics of the medical treatment process and explain how it is influenced by medical knowledge and patient related information. We consider the understanding of the nature of the medical treatment process and its parameters as fundamental for the ability to estimate the potential of IT to improve process quality.

3.1. Medical decision making

The medical treatment process is often denoted as diagnostic–therapeutic cycle (cf. Fig. 2) comprising observation, reasoning, and action. Each pass of this cycle is aimed at decreasing the uncertainty about the patient’s disease or the actual state of the disease process [77]. Thus, the observation stage always starts with the patient history (if available) and proceeds with diagnostic procedures which are selected based on available information. It is the job of an (*Electronic*) *Patient Record* to assist healthcare personnel in making *informed decisions*. Consequently, the system should present relevant information at the time of data acquisition and at the time of order entry. Thereby, an important question to be answered is how to determine what is relevant. Availability of relevant information is a precondition for medical decisions – *medical knowledge* guides these decisions.

Medical knowledge, however, is not limited to what is found in medical textbooks. Moreover, medical knowledge evolves over time. In some cases there are systematic literature reviews that describe evidence so compelling that the right thing to do is clear. Such strong evidence, however, is rare in medicine. Even if

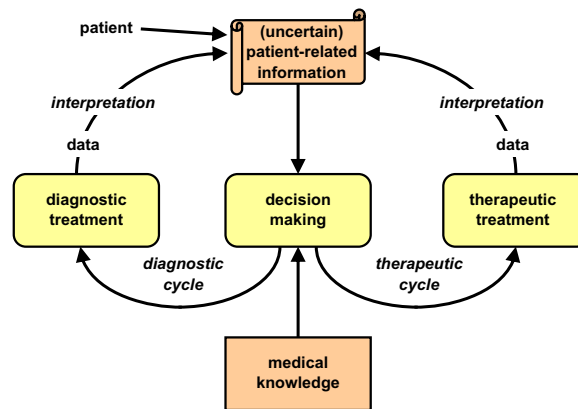


Fig. 2. Diagnostic–therapeutic cycle.

evidence is available, often enough it is hidden in the results of some clinical study and not readily applicable in a clinical context. And even if the evidence has been considered in reviews and found the way into consented guidelines, existing published recommendations for medical treatment need frequent revision as new evidence occurs. Following the principles of *Evidence based medicine (EBM)* physicians are required to formulate questions based on patients' problems, search the literature for answers, evaluate the evidence for its validity and usefulness, and finally apply the information to patients [26,29]. Of course, clinicians will typically not have the time to do such research while the patient is in the office; so, literature search will necessarily take place offline. On this basis EBM is nearly impossible to practice in everyday clinical care [61,67]. This raises the question whether medical knowledge can be provided in a more compact and applicable form and whether information technology can improve the practice of EBM by using such condensed knowledge? Medical guidelines are aimed at supporting clinicians in interpreting existing evidence by providing recommendations for decision making based on literature reviews and existing evidence.

EBM and guidelines are not aimed at establishing a “cookbook medicine” as many fear [61,76]. Instead, it means that physicians must know what they are doing as they have to individually estimate patients' chances and risks. Moreover, they have to ensure that their decisions are consistent with the patients' values, which is even more challenging [61]. Thus, physicians are not supposed to blindly follow some step by step treatment plan. Consequently, IT support cannot mean to enforce predefined step by step treatment plans, instead process support should contribute to provide the best available evidence to the physician in a readily understandable and applicable way. Such explicit medical knowledge is necessary but not sufficient for medical decision making. A large part of medical knowledge is not explicit but tacit [89], and tacit knowledge heavily influences information needs by care providers as well as the course of the care process [73,74].

According to Nonaka and Takeuchi [50] knowledge is created and expanded through social interaction between tacit and explicit knowledge. This process, called “knowledge conversion”, is a social process between individuals, rather than a process within an individual. Stefanelli describes this process of knowledge creation in the context of healthcare organizations [73]. In order to make medical knowledge broadly available, medical experts need to externalize their tacit knowledge. Thus, improving healthcare processes has a lot to do with stimulating and managing the knowledge conversion processes. As IT systems can only handle explicit medical knowledge we subsequently concentrate on this part, knowing that we can never automate decision making, because we will never be able to have the full picture at our hands.

3.2. Levels of explicit medical knowledge

Supporting the healthcare process by bringing explicit medical knowledge to the point of care is closely related to developing and implementing medical practice guidelines. The MeSH² dictionary defines medical

² MeSH: Medical Subject Headings. Thesaurus and controlled vocabulary used for indexing the MEDLINE database of medical literature provided by the National Library of Medicine (NLM).

practice guidelines as “work consisting of a set of directions or principles to assist the health care practitioner with patient care decisions about appropriate diagnostic, therapeutic, or other clinical procedures for specific clinical circumstances”. Guidelines are aimed at an evidence-based and economically reasonable medical treatment process, and at improving outcomes and decreasing the undesired variation of healthcare quality [25]. Developing guidelines is essentially a consensus process among medical experts. Yet, there is a gap between the information contained in published clinical guidelines and the knowledge and information that are necessary to implement them [25,72]. Methods for closing this gap by using information technology have been in the focus of medical informatics research for decades (e.g. [6,43,72]).

Medical pathways can be used as a basis for implementing guidelines [70] and sometimes they are confused with guidelines. In contrast to guidelines, pathways are always related to a concrete setting and include a time component: pathways are planned process patterns that are aimed at improving process quality and resource usage. Since pathways are site-specific they do also not constitute *standardized* generic processes like those described within the IHE integration profiles (cf. Section 2). Further, pathways need a consensus process. They must be tailored to local and individual circumstances, which requires a cooperative initiative of clinical experts, process participants, and managers. If restricted to a clinical setting we may also talk about clinical pathways instead of medical pathways. Pathways can be used as a platform to implement guidelines, e.g. by routinely collecting information required by a guideline. Selecting a guideline for implementation also requires an agreement of healthcare professionals and patients, because there are different kinds of guidelines with different origins and goals, and sometimes even conflicting recommendations. Likewise, to improve a patient treatment process across organizational borders, consensus on common practices is required in the first place.

Once this consensus is achieved, the next question is how to implement it in practice. To be effective, a guideline must be easily accessible. Ideally, it should be embedded into the clinical work practice, and the physician should not need to explicitly look it up. Otherwise, there is always a risk of overlooking important information while the patient is in the office. Previous work has primarily demonstrated a positive influence of computer-generated alerts and reminders [22,31,71], which can be integrated into clinical work practice. Recent research indicates that this is exactly the major difficulty with implementing more complex multi-step guidelines: how to integrate them into the clinical workflow [43,71,90]?

The influence of different levels of explicit medical knowledge on the patient care process is illustrated in Fig. 3. In this figure domain-specific medical knowledge (available in medical literature and consented in various kinds of guidelines) is distinguished from site-specific treatment plans. We use the term “treatment plan” as a synonym for clinical and medical pathways, in order to underline its site-specific character. Note that a treatment plan may consider many different guidelines, and that a guideline may be considered within multiple treatment plans. In addition, medical knowledge stemming from general guideline recommendations may also be reflected in alerts and reminders, which are independent from treatment plans: an alert (e.g., “Lab alert” for values that are out of bounds or for data values that are about to develop into dangerous areas) requires some kind of notification system to inform the responsible physician. Reminders can be used to inform the person who enters data instantaneously if data are entered which are not plausible or if expected data entries have not been made.

A treatment plan comprises multiple diagnostic or therapeutic steps (procedures). Instances of a treatment plan need to be adapted to the specific needs of an individual patient (individual treatment plan). The actual treatment process may still deviate from the individual treatment plan. Consequently, an IT system supporting the medical treatment process will have to take into account that treatment plans need to be handled in an extremely flexible way. A simplified illustration of the different levels of deviation is shown in Fig. 4.

We illustrate the different levels of deviation indicated in Fig. 4 by the following example: consider a patient with suspicion of proximal femoral fracture.³ There is no guideline for femoral fracture diagnosis, as most fractures of the proximal femur are easily diagnosed by conventional radiography. However, medical literature does suggest to use magnetic resonance imaging (MRI) to help reach a diagnosis when the images are

³ The femur is the bone between the hip and the knee. The proximal femur is the part near the hip. Proximal femoral fractures include a broad group of common fractures of the femoral head and neck typically occurring in osteoporotic females.

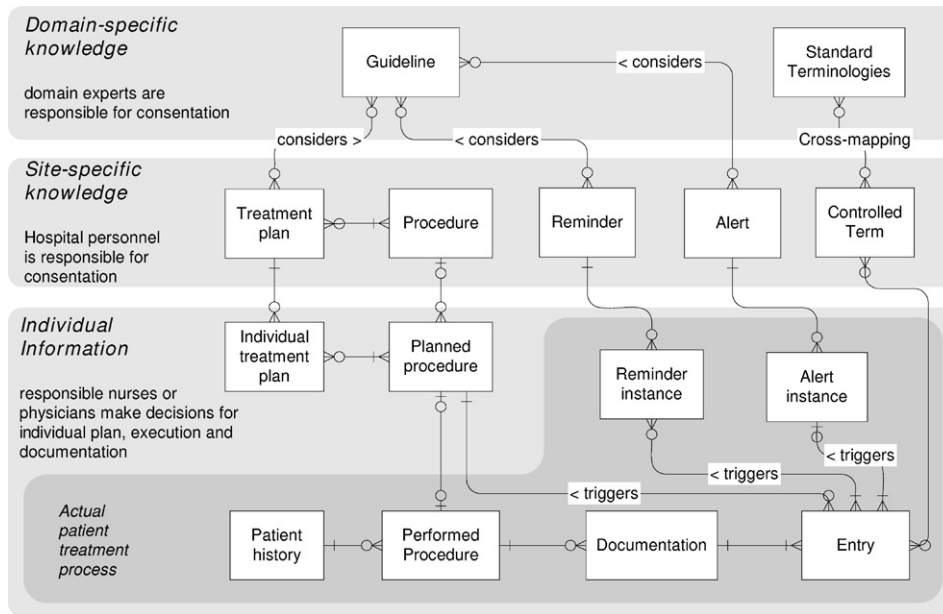


Fig. 3. Influence of explicit medical knowledge on the healthcare process.

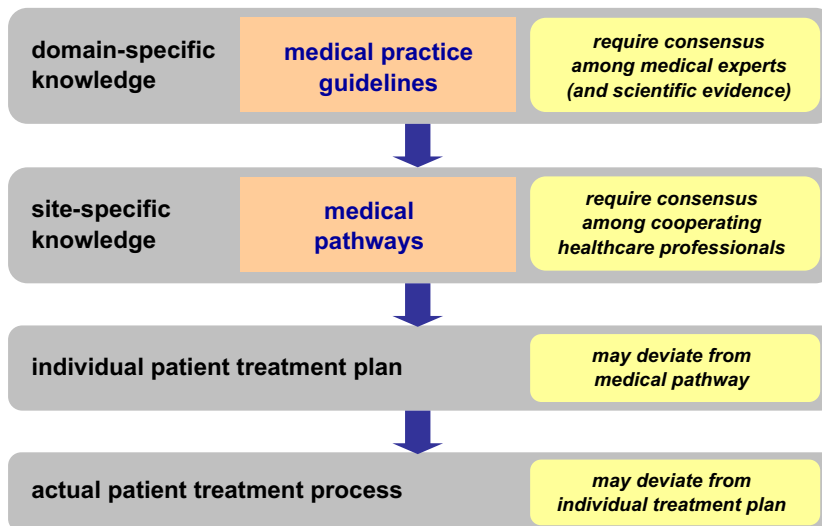


Fig. 4. Deviation of individual treatment from guidelines and treatment plans.

judged to be negative or equivocal and a clinical suspicion of fracture persists [23]. A site-specific medical pathway can only consider this recommendation if an MRI is actually available. Let us assume there is an MRI and the site-specific treatment plan recommends MRI diagnosis if conventional radiography has left any doubts; the individual treatment plan might still deviate from this recommendation because the patient might have an implanted pacemaker (PM) which might be negatively influenced by the MRI. In addition, even if treatment plans are individualized it must be possible to allow the actual treatment process to deviate from this individual plan. For example, it might not have been recognized that there is a contraindication for MRI when the plan was individually adapted.

| | organizational processes | patient treatment process |
|-------------------------------------|--|--------------------------------------|
| site-independent | generic process patterns (e.g., IHE integration profiles) | medical guidelines |
| site-specific adaptation | organization-specific workflows | medical pathways |

Fig. 5. Categorization of healthcare processes.

So far we have primarily distinguished between organizational processes and the medical treatment process. In addition we have to distinguish between general site independent recommendations and site-specific adaptations. Fig. 5 summarizes the resulting process categories according to these distinctions.

Supporting organizational processes by the use of IT is helpful, as organizational deficits are an important cause for Adverse Events (e.g. [79,12]), but it is only a part of the potential of IT to improve healthcare processes. Supporting the complex process of medical decision making is much more challenging. Subsequently we briefly summarize what has been done so far in this context.

3.3. Achievements in decision support

Medical decision making must integrate best available evidence with personal experience and patients values. Information technology can support such decision making in various ways. Some documented examples are:

- (1) Computer systems can contribute to improve different aspects of data quality, e.g. completeness [28], timeliness [78], etc. thereby improving the information basis for decision making.
- (2) Computer systems can contribute to better monitor the current status of a patient, e.g. by presenting patient data in a more coherent way, by providing optimized views to patient data for dedicated purposes, or by generating alerts if some parameter or a combination of parameters is developing into dangerous areas (e.g. [4]).
- (3) Computer systems can detect mismatches between existing guidelines and the actual patient treatment process, e.g. contraindications for some planned procedure.
- (4) Computer Systems can generate reminders to ensure that planned actions are not forgotten [44].⁴
- (5) Computer systems can calculate drug doses from previously entered data (e.g. age, weight, gender), check compatibility with other medications, and check compatibility with allergies [3,49]. Computerized *Physician Order Entry systems (CPOE)* are estimated to reduce medication errors up to 81% [36].
- (6) Computer systems can calculate disease probabilities [27].

All these techniques require the computer to be able to make use of the patient's clinical data according to current medical knowledge. The first obstacle to achieving this is to represent medical knowledge in a computer-interpretable form, i.e., translating narrative guidelines into equivalent ones that use coded data. This is cumbersome and also bares the risk of distorting the intent of the original guideline. The second obstacle is to keep medical knowledge maintainable. Thus, separating this knowledge from computer applications is desirable.

To overcome such problems numerous models have been developed to formally represent medical guidelines and medical knowledge (e.g., Arden Syntax [30], GLIF [52,54]). Recent surveys have compared these approaches [18,55,19]. One of the central goals is to define standard representation formats for medical knowledge in order to be able to share guidelines among different information systems in different organizations. In practice, however, it turned out that the main obstacle to be solved here is – once again – an integration prob-

⁴ Note that computer systems should not be used to *enforce* some pre-planned action!

lem: the data definitions in pre-defined formal guidelines may not map to the data available in an existing electronic health record system [56]. Typically, operational systems have to be modified and extended in order to acquire the necessary information needed for guideline implementation. Few guidelines have been successfully implemented into real clinical settings by using these systems and predefined formally specified guidelines. Recent research has recognized these difficulties and focuses on process models for transforming textbased guidelines into clinical practice [72]. Standard formats for guideline representation do have their place in guideline implementation, but the integration problems to be solved are a matter of semantics rather than format.

Guideline implementation requires a high level of data integration, because computerized reminders typically refer to both type and instance level semantics. More complex guidelines also need to refer to a formally established context comprising status information. The challenge to be solved for distributed healthcare networks is to establish a sufficient degree of integration as basis for guideline implementation, and to find practical solutions to cope with the continuously evolving healthcare domain. Thereby, it is important to keep in mind that medical decision making is complex, and that simplified technical solutions might be counterproductive, as computer applications that are not well accepted or insufficiently integrated into clinical work practice are in danger of provoking dangerous workarounds [36,5].

So far, IT support for medical decision making is not so much “process-oriented”. Implementing guidelines by translating them into alerts and reminders has proven to be effective if certain preconditions are considered [5], but it does not recognize the patient treatment process as a unit. Medical pathways, as introduced above, are an attempt to actually provide some kind of process template. Thus, the next question is, how can we effectively provide IT support for medical pathways. Subsequently we describe an example of a clinical pathway that has been improved by an integrated IT application.

4. IT support for clinical pathways: example

In Section 3 we already mentioned the example of proximal femoral fracture to illustrate the different levels of deviation. This example is only one out of very many aspects which had to be considered when a clinical pathway for patients with suspicion of proximal femoral fracture was successfully implemented at the University hospital in Marburg (cf. [8–10,69]). A simplified illustration of this pathway is shown as activity diagram in Fig. 6. Implementing a pathway like this in practice requires to overcome many types of barriers in order to actually improve the quality of patient care. It is important to analyze the current deficiencies and the barriers to change prior to pathway implementation. As a typical barrier clinicians might not know about the best available evidence or current guideline recommendations. Thus, teaching is very important in the context of consenting a clinical pathway (“academic detailing”).

Once the pathway is consented we can think about how to improve pathway compliance by the use of IT. In the case of the example mentioned above some critical steps have been selected for IT support. A core requirement for IT support was to reduce the necessary computer interaction as much as possible, because clinicians typically act under time pressure and will not accept any computer application that takes too much time away from patients.

One approach to reduce documentation overhead was to use checklists which are pre-filled to some degree according to pathway recommendations. This allows to do pathway conformant documentation easily with a few clicks; deviation from the pathway is not prohibited but has to be documented additionally. Structured data stemming from the initial pathway documentation is used to parameterize and trigger generic interdisciplinary processes, like imaging diagnostics. This means: once the physician has entered suspicion of proximal femoral fracture, a pathway conformant order set for radiography is automatically created. The clinician can individually correct this order set before sending it to the radiology department.

The described example has been implemented at Marburg University Medical Center on the basis of an extensible integrated hospital information system [39,41]. As mentioned before, integration is an important precondition for process support, because data stemming from different departments needs to be readily available for reuse in order to be able to provide effective decision support. To achieve this integration, the Marburg Hospital Information System is based on a commercially available holistic system. Extensibility is achieved via a CASE tool, which can be used to implement adapted clinical applications on a rapid prototyp-

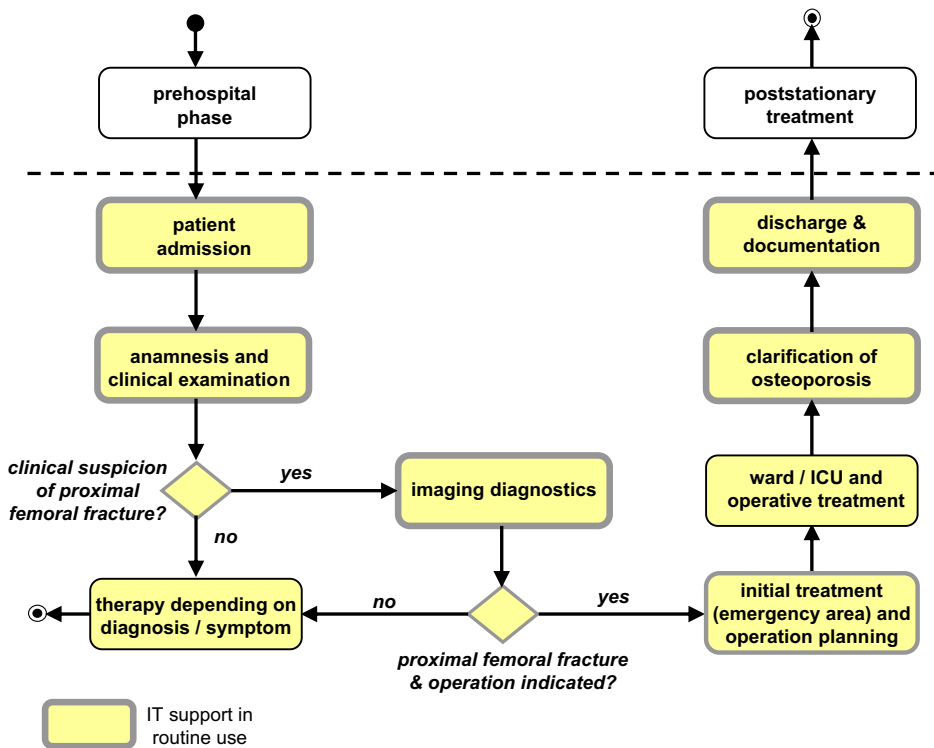


Fig. 6. Clinical pathway for proximal femoral fracture (simplified) [9].

ing basis. Such newly developed clinical applications have the advantage of being integrated with the overall system from the beginning. The disadvantage of the approach is that the implementation of workflow is limited to the capabilities of the proprietary CASE tool. Tool-generated adapted applications are mainly based on workflow-enabled electronic forms which are integrated with the rest of the system via a common database. A major precondition for placing reminders and alerts or for automatically parameterizing order sets is the potential of a system to reuse structured coded data. In Marburg this was achieved by storing all coded data in the central database. From here data can be automatically uploaded into dedicated electronic forms – such as the form for order placement.

The implementation of the example has shown that improving clinical pathways by the use of IT is possible. The pragmatic approach followed in Marburg has also shown, however, that there is still a huge potential to improve IT architectures to better suit for supporting clinical processes. For example, due to restrictions of the integrated CASE tool used, document flow had to be hard-coded into electronic forms. Certainly, a separation of workflow specifications and form contents is desirable to improve maintainability of clinical applications. In general, more flexible process support and easy adaptability to change are required in order to provide full process lifecycle support [66].

5. Implications for process-oriented IT architectures

The support of healthcare processes raises a number of requirements and challenges for process-oriented IT architectures. In particular, integrated process support, information management, and knowledge management on different levels are needed. Current healthcare information systems have failed in meeting these requirements. This, in turn, has led to pragmatic solutions and workarounds in order to reduce the overall effort for integrating heterogeneous application components and to enable a requirements-driven system evolution. In this section we take a more visionary viewpoint. We discuss basic issues related to the computerized support of both organizational processes and patient treatment processes.

5.1. Support for organizational processes

Though current hospital information systems partially support (fragments of) clinical workflows the process logic is more or less hard-coded in the application programs. This, in turn, has led to unsatisfactory process support (e.g., no monitoring facilities), high maintainability costs, and low system flexibility. In order to support organizational processes (cf. Section 2) and to provide the needed information at the point of care, IT architectures in hospitals must consider the cross-departmental nature of clinical processes. To avoid media breaks we either need highly integrated systems or semantically compatible application components. Semantic compatibility, in turn, subsumes information and functional integration. Besides this, comprehensive system support is needed for tasks related to organizational and administrative processes. Process support functions should comprise standard system services (e.g., process enactment, process monitoring, worklist management) as well as advanced features (e.g., ad hoc changes of single process instances during runtime [57] or management of temporal constraints [17,68]).

Organizational processes in hospitals are part of the fundamental work procedures in clinical practice, which basically show less variability and dynamics when compared to the patient treatment process. Therefore workflow management systems (WfMS) [81] offer a promising approach for implementing site-specific, organizational processes. WfMS enable the definition, execution, and monitoring of well-structured processes [21]. In connection with Web service technology, in addition, the benefits of process automation and optimization from within a single hospital can be transferred to cross-organizational processes as well [2]. By separating the process flow logic from the application code (i.e., the application functions), in principle, organizational processes can be quicker implemented and adapted when compared to conventional approaches (cf. Section 4). The experiences we made when implementing workflow-based clinical applications have confirmed this [58]. Since site-specific customizations and adaptations frequently become necessary in healthcare, vendors of hospital information systems more and more adopt process management technologies.

Though WfMS have shown promising perspectives when being applied to organizational processes in healthcare [58], still a lot of features are missing. Integrated time and resource management, for example, are urgently needed in healthcare, but have not been adequately addressed in existing WfMS [17]. The same applies to more advanced system functions like, for example, the personalized visualization of process instances [11] or the extension of the classical worklist paradigm (e.g., support of multi-actor tasks). WfMS also lack adequate support for defining and maintaining process model configurations. Think of, for example, a ward which has to accomplish numerous diagnostic and therapeutic procedures with different departments. Though order handling and result reporting are similar in all these cases, there are smooth differences regarding the concrete process logic and the involved application components. Altogether we may obtain a large number of different configurations for the same basic organizational process. In current WfMS each of these configurations has to be defined and maintained in a separate process template, and even simple organizational changes may require manual re-editing of a large number of such templates. Over time this leads to a degeneration and divergence of the different process configurations. This, in turn, significantly aggravates future adaptations, ultimately making a refactoring of the existing process configurations inescapable.

5.2. Support for patient treatment processes

The integrated support of medical pathways and their individual adaptation (cf. Fig. 4) constitute a fundamental task for process-aware information systems in healthcare. Such process awareness could be particularly beneficial if it is aimed at a full process lifecycle support and meaningful feedback at the different process levels (see below).

To support guideline dissemination and to improve the transfer of evidence into clinical routine reliable sources of evidence must be provided in easily accessible repositories. Such repositories are beginning to emerge (e.g. [16]) but still numerous sources with heterogeneous and partly contradictory contents exist. In any case, site-specific process optimization can be improved by providing more transparency on existing evidence. The medical pathways resulting from site-specific adaptations of existing evidence then provide the basis for the computerized support of patient treatment processes. They also link patient treatment processes to organizational process patterns as well as to operational systems (incl. access to electronic patient records).

Based on this, new process instances (representing concrete patient treatment cases) can be created and corresponding activities be coordinated. However, users must be able to adapt medical pathways to the specific situation of their patients whenever needed.

No adequate system support for integrated pathway management has been provided so far. A major reason for this deficiency is the rigidity of existing WfMS, which are unable to cope with the evolving nature and the dynamics of patient treatment processes. However, problems are not only related to technology, but also deal with knowledge acquisition, knowledge maintenance, and legal responsibilities. Finally, as we elaborated in the previous sections, process alignment has to be seen as the core challenge: embedding IT support into clinical routine. IT should always be seen as a supportive tool, but it should never hinder clinical processes, even in the case of system failures.

5.2.1. General remarks

The handling of medical pathways requires an organization-specific consensus among medical staff. Before we try to support medical processes by means of IT we must be aware that this can only work if IT support is aligned with an overall organizational change management process, which includes consensus processes, academic detailing and training of healthcare professionals. Due to the evolving nature of medical knowledge, in addition, process-oriented IT architectures must enable continuous adaptation. This should be accomplished under control of the respective healthcare organization. Furthermore, patient treatment processes (and their monitoring) as well as patient information must be linked to the defined pathways and the underlying sources of evidence.

IT architectures, which support medical processes, should allow for the explicit definition of medical knowledge and enable its combined use with patient-related information. This requires a minimum of semantic control. In order to avoid problems at the operational level (e.g., when linking pathways with patient information), we need tools for defining pathways based on the medical concepts and the medical terminology already used within the operational systems. This requires standardized ontologies and vocabularies, which partially exist in medicine. Furthermore, we must consider the evolving nature of the healthcare domain itself; i.e., we must support the evolution (and versioning) of the ontologies and controlled vocabularies to which pathways refer.

5.2.2. Lifecycle support for guidelines and pathways

We sketch what we mean with full lifecycle support for treatment processes, and we discuss how it could be supported with adaptive process management technology [32,57]. We do not focus on technical issues (which have been extensively described in other papers), but simply want to illustrate a challenging application area for process management technology. Our framework for integrated guideline and pathway support is depicted in Fig. 7. We summarize basic characteristics of this framework referring to the numbers in Fig. 7.

Guideline formalization. To some extent guidelines are comparable to reference models in business process management; however, they tend to be more complex and need to be adapted more frequently. Usually, guidelines are published by a scientific organization in narrative form, e.g., as text or hypertext document. A first step towards computer-based process support therefore is the formalization of the guidelines and their representation in a machine-understandable way (1). Ideally, this can be accomplished by the same organization which has developed and delivered the guideline. We need tools for (graphically) specifying the guidelines at a semantically high level and in a form understandable to domain experts. Basically, established process description formalism (e.g., High-level Petri Nets [51,81] or Activity Diagrams [20]) can be applied in this context. As mentioned, in addition, guideline definitions should be based on standardized medical concepts and medical vocabularies.

Guideline dissemination. When a new version of a medical guideline is released it has to be published and disseminated (2). Note that the goal cannot be to automate guideline dissemination, but to improve transparency concerning existing evidence. To support guideline discovery a process-oriented IT architecture should have access to repositories at different levels (local, regional, national, international).

Deriving site-specific pathways. Site-specific adaptations of medical guidelines require a consensus among the corresponding healthcare professionals. Based on this, engineers can design a site-specific medical pathway schema P (3), i.e., a schema which describes the logic of a particular treatment process independent of concrete

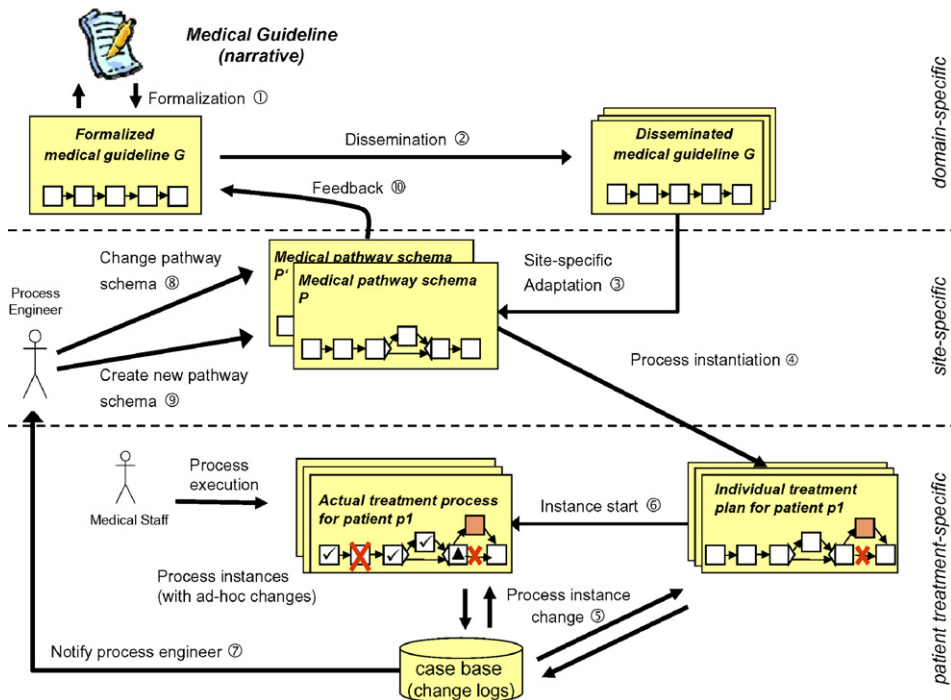


Fig. 7. Required lifecycle support for medical guidelines/pathways.

treatment cases or patient situations. In particular, a pathway schema must be linked to the operational systems of the healthcare organization and to the electronic patient records it maintains.

Creating an individual patient treatment plan. Based on a medical pathway schema new instances of patient treatment processes can be created (4). Before such a new process instance (i.e., treatment case) is started, the used pathway schema P may have to be adapted to the specific situation of the patient (by applying a set of change operations) (5). Due to such treatment- or patient-specific adaptations, an individual patient treatment plan results, which deviates from the medical pathway it was derived from.

Executing and adapting patient treatment processes. Based on an individualized patient treatment plan, a corresponding treatment case (i.e., process instance) can be started and executed (6). However, the resulting process instance may be subject to change at a later point in time as well. Variations in the course of a patient treatment process are deeply inherent to medicine, and the unforeseen event is to some degree a “normal” phenomenon. Medical personnel must be free to react and is trained to do so. Therefore, in addition to the customization of a pathway schema at instance creation time, it must be possible to dynamically adapt in-progress treatment cases (i.e., process instances) during runtime. For example, authorized users should be allowed to add, delete, or move process steps (5). As a consequence the actual patient treatment process may deviate from the original treatment plan and the related medical pathway respectively. However, such deviations from the pre-planned process must not lead to errors or inconsistencies. Tools enabling them must be easy to handle, self-explaining and – most important – their use in exceptional situations should be not more cumbersome and time-consuming than simply handling the exception by a telephone call to the right person.

Instance-specific deviations (introduced at instance creation time or during runtime) have to be recorded (5). Thereby, not only syntactical information should be captured, but also semantic information about the reasons and context of a change. On the one hand this enables process engineers to derive optimized pathway schemes later on, on the other hand it allows for the reuse of changes. In healthcare any deviation from the standard procedure has to be documented for legal reasons.

The pathway enactment system must assist clinicians in defining and performing the necessary process changes at the different levels (and to accomplish them in a correct and consistent manner [57]). This necessitates intelligent user interfaces. On the one hand it must be possible to define ad hoc changes at a semanti-

cally high level, on the other hand the system should support the reuse of knowledge about previous changes and its application in similar situations (5); i.e., users should be able to draw on past experiences.

Organizational learning. A logical next step is to continuously monitor, analyze, and mine the change logs and to “learn” from the applied changes. Doing so one may detect that certain adaptations have occurred over and over again. In such cases, it is very likely that the respective changes are of interest for future process instances as well. Therefore, process engineers receive a corresponding notification (7) in order to decide whether the change shall be lifted up one level by changing an existing pathway schema (8) or by introducing a new one (9). Altogether this may result in optimized and locally tuned models for medical pathways. Finally, site-specific experiences should be communicated to the guideline consensus groups as well in order to indicate potential modifications of the original guideline (10) or to trigger new trials in order to gain more evidence.

Pathway adaptation and change propagation. As discussed it must be possible to adapt pathway implementations to changes in the local environment or to new evidence. Ideally, in such cases it is possible to migrate already running treatment processes to the changed pathway schema as well. The latter becomes necessary due to the long-running nature of patient treatment processes (up to several weeks or months). In this context pathway changes may also have to be propagated to individually modified treatment processes.

5.2.3. Enabling technology for lifecycle support

Taking commercial process management technology and WfMS the described framework could not be realized due to the mentioned drawbacks. However, in recent years several approaches have emerged which allow to (dynamically) adapt processes at different levels (e.g., the process type and the process instance level [15,33,37,48,47,57,64,62,63,80,85,86]) and to learn from these changes [66,84]. Note that this is exactly what we must expect from a process oriented IT platform, which can be used as the basis of a process aware information system to support evolving healthcare processes.

In the ADEPT project, for example, we have been working on the design and implementation of a next generation process management system (PMS) for several years (e.g., [57,59,64,60]). Though ADEPT provides an application-independent approach, many of its advanced process support features (e.g., enabling ad hoc change of single process instances or process schema evolution) have been motivated by requirements we identified in case studies conducted in the clinical domain (see [17,58]). More precisely, besides standard process management functions (e.g., process monitoring, worklist management), the ADEPT system enables dynamic changes of different process aspects (e.g., control and data flow) during runtime. Such process changes always preserve correctness properties and semantic constraints, and can be performed at two different levels – the *process type* and the *process instance* level [64,65].

Ad hoc changes of single process instances. ADEPT supports different kinds of ad hoc process instance changes (e.g., to insert, delete, or shift activities) [57]. This is exactly the functionality we need to derive patient-specific treatment processes from a pre-defined clinical pathway schema and to further adapt them at execution time if needed. In ADEPT, such ad hoc changes do not lead to an unstable system behavior, i.e., none of the guarantees (e.g., regarding the absence of deadlocks) achieved by formal checks at buildtime are violated due to the dynamic change. This kind of robustness is essential for any process-aware healthcare information system. ADEPT offers a complete set of operators for defining instance changes at a high semantic level and it ensures correctness by introducing pre-/post-conditions for these operations. All complexity associated with the adaptation of instance states, the remapping of activity parameters, or the problem of missing data (e.g., due to activity deletions) is hidden to a large degree from users. Finally, all ad hoc deviations are documented and stored in change logs. In healthcare, for example, this documentation is needed for legal reasons.

In order to support change reuse in the ADEPT framework we have adopted concepts and techniques from case-based reasoning (CBR), which is a contemporary approach to problem solving and learning [35]. New problems are dealt with by drawing on past experiences – described in cases – and by adapting their solutions to the new problem situation. In our scenario this means that users can retrieve the context of and the actions related to previous ad hoc changes, and can reuse this knowledge when defining new ad hoc deviations [66]. Generally, reasoning based on past experiences is a powerful and frequently applied way to solve problems by humans [1]. Particularly, in healthcare this is essential to adequately assist non-experienced clinicians. Obvi-

ously, such an advanced approach requires the formalization of problem descriptions as well as of the corresponding actions. In future, we additionally aim at the semantic annotation of change logs and the mining of these logs to discover process model optimizations. This will enable organizational learning as described before.

Process type changes and change propagation. In order to deal with business process changes (e.g., the adaptation of a medical pathway to organizational changes) ADEPT enables quick and efficient schema adaptations at the process type level (*process schema evolution*). In this context it is also possible to propagate process type changes to running process instances (of this type) [62]. This is particularly important for long-running processes as in the case of patient treatment. ADEPT guarantees that only those process instances can be migrated to the new process schema version, which are *compliant* with this schema [62]. Further, the states of compliant instances are automatically adapted when migrating these instances to the changed process schema. ADEPT is able to efficiently handle a large number of concurrently running process instances. It is also possible to propagate process type changes to unbiased as well as biased process instances. We denote process instances as *unbiased* if they are running according to the original process type schema they were derived from, whereas process instances are denoted as *biased* if they have been individually modified (e.g., due to an ad hoc change) [65]. Note that actual patient treatment processes often represent biased process instances when compared to the original pathway schema.

6. Summary

The potential of IT to prevent medical errors and thereby improve healthcare quality is undeniably attractive. Yet, to adequately support healthcare processes it is important to understand their characteristics. To identify the core challenges as well as the shortcomings of current IT approaches we distinguished organizational processes from the medical treatment process. While organizational processes are based on more or less stable generic process patterns the patient treatment process depends on medical knowledge which rapidly evolves. Appropriate IT support for the latter is difficult to achieve, because medical decision making is based on both tacit and explicit knowledge and cannot be automated. Evidence Based Medicine (EBM) is supported by guidelines which contain general recommendations based on current evidence and expert consensus. Medical pathways require a consensus among process participants in a particular healthcare setting in order to adapt existing guidelines to local circumstances and preferences. Before IT can effectively support such pathways physicians should be aware of the underlying evidence. Once these preconditions are fulfilled, IT can contribute to improve pathway compliance if it is carefully embedded into routine work practice. The goal of IT support for healthcare processes is not to control the course of the process, but to assist healthcare professionals by reducing cognitive overload and improving the basis for their decisions.

Current IT solutions support organizational process patterns to some degree, as standards like HL7 and IHE help to integrate heterogeneous system components. Yet, continuously adapting systems to site-specific requirements and ever changing needs for decision support is an open challenge. We demonstrated that one precondition for such an evolutionary approach is a high degree of flexibility. The ADEPT PMS does provide such flexibility, thus it appears to be suitable to improve IT support for healthcare processes. However, ADEPT is not a healthcare application. It rather has to be seen as a powerful workflow engine supporting healthcare applications on top of it. These applications must enable healthcare professionals to easily specify and maintain the medical knowledge contained in medical pathways, alerts, and reminders. In addition, different kinds and degrees of decision support are required, as experienced healthcare professionals will certainly need another kind of support as an inexperienced newcomer. Numerous challenges still exist which must be carefully understood and which require basic research before we can come to a complete solution approach. We believe that realizing process-oriented IT architectures in healthcare is a great challenge for the business process management community – if not even the “killer application” for this type of technology. In any case different levels of process support have to be distinguished and a high degree of variability and dynamics has to be achieved.

Future healthcare information systems must also support patient treatment and information management in distributed healthcare networks. Healthcare is more and more changing from isolated patient treatment episodes towards continuous treatment involving multiple healthcare professionals and institutions. Therefore

hospitals need to be linked with other healthcare organizations and general practitioners, but also with insurance companies and governmental organizations, over wide area networks transporting sensitive patient data. The adequate support of distributed healthcare networks will result in novel process scenarios raising a number of challenging issues. A sufficient degree of process and information integration and the semantic interoperability of the different healthcare systems are crucial in this context. The same applies to privacy and security issues in connection with the exchange of patient data.

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